

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

All Actions

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION
TO TORRENT PHARMACEUTICALS LIMITED AND TORRENT PHARMA INC.
PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: **Alexia Brancato
Brittney Nagle
Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022**

Counsel for Defendants Torrent Pharmaceuticals Limited and Torrent Pharma Inc.

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of Kelly Gegenheimer, Vice President Sales, as designated corporate representative with regard to the topics 34-35, 37, 41-45 as set forth on Exhibit A attached hereto. The deposition will commence on **Thursday, February 25, 2021, at 9:00 a.m. Eastern Standard Time**, at Kirkland & Ellis, LLP, 601 Lexington Ave., New York, NY 10022, via zoom, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

TAKING ATTORNEYS FOR PLAINTIFFS:

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DATED this 27th day of January, 2021.

LAW OFFICES OF GEORGE A. BARTON, P.C.

By: /s/ Stacy A. Burrows
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CERTIFICATE OF SERVICE

I, Stacy Burrows, hereby certify that on January 27th, 2021, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Torrent Pharmaceuticals Limited and Torrent Pharma Inc., and Defendants' liaison counsel, via email.

DATED this 27th day of January, 2021.

LAW OFFICES OF GEORGE A. BARTON, P.C.

By: /s/ Stacy A. Burrows

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Attorneys for Plaintiffs

EXHIBIT A

All topics reference information and documents known to, and/or in the possession, custody, or control, of Torrent, in the ordinary course of its business.

All references to Torrent include Torrent Pharmaceuticals Limited and Torrent Pharma Inc.

All references to the finished dose or Torrent's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by Torrent, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Torrent API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)

- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

Testing of Valsartan API and Finished Dose

1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
3. The testing performed by Torrent or its agents, to evaluate the purity and contents of ZHP's API.
4. The testing performed by Torrent or its agents, to evaluate the purity and contents of Torrent's finished dose.
5. The testing performed by any entity or person other than Torrent or its agents but known to Torrent, to evaluate the purity and contents of ZHP's valsartan API.
6. The testing performed by any entity or person other than Torrent or its agents but known to Torrent, to evaluate the purity and contents of Torrent's finished dose.
7. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of ZHP's valsartan API.
8. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of Torrent's finished dose.
9. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of ZHP's valsartan API.
10. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of Torrent's finished dose.
11. Torrent's evaluation of the potential risks to the purity or contents of ZHP's API posed or caused by solvents used during the API manufacturing process.
12. Torrent's evaluation of the potential risks to the purity or contents of Torrent's finished dose posed or caused by solvents used during the finished dose manufacturing process.
13. The chromatogram and mass spectrometry or other results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API.
14. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of the solvents utilized in the manufacture of Torrent's finished dose.
15. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than ZHP or its agents but known to Torrent, of the solvents utilized in the manufacture of ZHP's API.

16. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of the solvents utilized in the manufacture of Torrent's finished dose.
17. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of the production equipment utilized in the manufacture of Torrent's finished dose.
18. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of the production equipment utilized in the manufacture of Torrent's finished dose.
19. The extent of the actual and potential nitrosamine contamination of Torrent's valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

Quality Assurance and Quality Control Activities

20. Torrent's SOP's/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of valsartan API.
21. Torrent's SOP's/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Torrent's finished dose.
22. Torrent's application of cGMPs in connection with the manufacture of Torrent's finished dose.
23. Deleted.

Process Development

24. Deleted.
25. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API.
26. Any evaluation conducted by or on behalf of Torrent with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, and in particular potential nitrosamine impurities, in the manufacturing process for ZHP's valsartan API.
27. Torrent's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API.
28. Torrent's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API.
29. Deleted.

Communications with Regulatory Agencies

30. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
31. Torrent's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
32. Torrent's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of Torrent's valsartan finished dose with nitrosamines including NDMA and NDEA.

Torrent's Communications with API Manufacturers and Downstream Customers

33. Torrent's oral and written communications with ZHP with regard to the content/purity/contamination of ZHP's valsartan API.
34. Torrent's oral and written communications with its valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Torrent finished dose.
35. Torrent's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Torrent's finished dose.
36. Torrent's product recall for valsartan finished dose, including who Torrent communicated with, how, about what, and the retention of recalled or sequestered valsartan finished dose.
37. All credits, indemnification, refunds, and/or penalties paid or provided by or to Torrent in connection with the nitrosamine contamination of valsartan (for example: Torrent-MDL2875-00100153).

Compliance with cGMPs

38. Torrent's compliance or non-compliance with cGMPs as it relates to the manufacture, quality assurance, quality control, and sale of Torrent's finished dose.
39. Deleted.

Product Tracing

40. Tracing of batches and lots of Torrent's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
41. The pricing of Torrent's valsartan finished dose that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).
42. The gross and net profits to Torrent from the sale of Torrent's valsartan finished dose in the United States (the parties to meet and confer to identify relevant documents).

43. The quantity/units of Torrent's valsartan finished dose sold in the United States (the parties to meet and confer to identify relevant documents).
44. The Torrent valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).

Corporate Relationships

45. Torrent's acquisitions and ownership of entities that purchased valsartan API and sold valsartan finished dose intended for use in the United States.